CLINICALDESIGN

Instructions for Use

UTS Tube 5ml™

Σ 50

Table of Contents:

CE UKCA IVD

1. Introduction

A non-sterile single-use specimen receptacle for the containment of a urine specimen during urinalysis.

For *in vitro* diagnostic use by a Healthcare Professional only.

1.1 Intended Purpose.

The UTS Tube 5ml™ is a single-use specimen receptacle with lid intended for the containment of a specimen during *in vitro* diagnostic examination of analytes in a urine sample. No additive present.

The lid is designed to connect the tube to a UTS -10 Cap™ which is inserted into a UTS Digital Analyser™ that provides the *in vitro* qualitative or semi-quantitative determination of urine analytes displayed as digital results.

The UTS Tube 5ml™ is intended for use by a Healthcare Professional in a near-patient setting.

1.2 Summary

The UTS Tube 5ml™ is intended to be used in combination with the UTS-10 Cap™ and UTS Digital Analyser™ for the *in vitro* diagnostic examination of analytes in a urine specimen.

The UTS-10 Cap™ is a single-use push fit testing cap that contains reagent pads for ten (10) parameters, Glucose, Blood, Bilirubin, Ketone (Acetoacetic Acid), Specific Gravity, pH, Protein, Urobilinogen, Nitrite and Leukocytes used to detect specific urine analytes **– Product Name and Code: UTS-10 Cap™ (UTSCA01)**

The UTS Digital Analyser™ is a semi-automated *in vitro* diagnostic reflectance photometry device, designed to support the performance of the UTS-10 Cap™ that detects specific urine analytes by presenting the results as digital results on a display **– Product Name and Code: UTS Digital Analyser™ (UTSDA01)**

2 Device Procedure

The UTS Tube 5ml™ should be used with a urine specimen only.

For the most accurate results, a first of the day, mid-stream urine specimen is recommended but specimens taken at other times during the day are acceptable, according to local policy.

Step 1. Use an appropriate specimen collection receptacle to collect a freshly voided urine specimen, according to local policy.
Step 2. Using a Transfer Pipette, fill the UTS Tube 5ml™ with the urine specimen up to the middle line indicated on the UTS Tube 5ml™.
Step 3. Securely screw the lid onto the UTS Tube 5ml™.

Continue with test procedure detailed in the Instructions for Use (IFU) for the UTS-10 Cap™ **– Product Name and Code: UTS-10 Cap™ (UTSCA01)**

See Section 6 for additional Specimen Collection and Handling

3 Materials

The UTS Tube 5ml™ is intended for use in combination with the UTS-10 Cap™ and UTS Digital Analyser™.

Contents of packaging:
50 x Clear Test Tube with white label
50 x White screw lid

uts™ Urine Testing System

CE UKCA IVD

Devices required to perform a test:

Provided:

1 x UTS Tube 5ml™

Not Provided:

1 x UTS-10 Cap™
UTS Digital Analyser™

Specimen Collection Container
Consumables (i.e. Transfer Pipette, PPE/ gloves)

Please follow applicable internal procedures in accordance with local or national regulations.

4 Storage

Store as packaged in a clean and dry area.

The date of manufacture is printed on the UTS Tube 5ml™ packaging, the UTS Tube 5ml™ must be used within 5 years from the date of manufacture.

5 Warnings and Precautions

For *in vitro* diagnostic use only by a Healthcare Professional. Not sterile.

- UTS Tube 5ml™ must be used with the supplied lid only.
- The Instructions for Use (IFU) must be read and understood completely before performing the test.
- Handle all specimens as if they contain infectious agents.
- Observe established precautions against handling of urine specimens throughout testing and follow the standard procedures for proper disposal of specimens.
- Wear appropriate protective clothing such as disposable gloves when specimens are handled.
- The used specimen should be discarded according to local or national regulations.
- The urine specimen must be allowed to equilibrate to room temperature before testing.
- Please ensure that an appropriate amount of specimen is used for testing. Ensure that the UTS Tube 5ml™ has been filled up to the middle line indicated on the UTS Tube 5ml™. Too much or too little specimen size may lead to invalid or no results.
- Do not use the UTS Tube 5ml™ if there are any visible signs of damage to the device.

Please comply with applicable internal procedures in accordance with local or national regulations.

6 Specimen Collection and Handling

The UTS Tube 5ml™ should be used with a urine specimen only. There is no additive present.

As per local policy, use an appropriate specimen collection receptacle to collect a freshly voided urine specimen and then using a Transfer Pipette, fill the UTS Tube 5ml™ with the urine specimen to the middle line indicated on the UTS Tube 5ml™ before securely screwing the lid onto the UTS Tube 5ml™.

For the most accurate results, a first of the day, mid-stream urine specimen collected at the point of care and tested within 2 hours is recommended. However, specimens taken at other times in the day are acceptable. Allow the test specimen to equilibrate to room temperature before testing.

See Section 5 for Warnings and Precautions before using the UTS Tube 5ml™.

7 Disposal

Dispose of unused or expired UTS Tube 5ml™, human specimens and consumables according to local or national regulations.

NOTE: Handle all specimens as if they contain infectious agents.

See Section 5 for Warnings and Precautions before using the UTS Tube 5ml™.

8 Troubleshooting and Support

Please contact your local/ regional distributor for assistance.

NOTE: Any serious incident that has occurred in relation to this device should be reported by the user to the manufacturer (quality@clinical.design) and the competent authority of the Member State in which the user and/or the patient is established.

9 Manufacturer

Clinical Design Technologies Ltd
Wessex House, Teign Road, Newton Abbott
Devon, England (UK), TQ12 4AA
www.clinical.design
email: info@clinical.design
Tel: +44 (0)132 635 2054

10 Copyright Notice and Policy Statement

Policy Statement
The information in this Instructions for Use (IFU) was correct at the time of printing. However, Clinical Design Technologies Ltd continues to improve products and reserves the right to change specifications, equipment, and maintenance procedures at any time without notice.

Copyright Notice

11 Symbols

SYMBOL	DEFINITION
	Manufacturer and Address Details.
	Please consult IFU
CE	CE Mark for European Conformity
UK CA	UKCA Mark for Great Britain
	Date of Manufacture (CCYY-MM)
IVD	*in vitro* Diagnostic Medical Device
LOT	Batch Code/Lot Number
REF	Catalogue Reference/ Product Code
	Near Patient Testing
UDI	Unique Device Identifier
Σ	Sufficient for / Tests per kit
	Single-use/ Do not Reuse
EC REP	EU Authorised Representative
	EU Importer

EC REP

MedEnvoy Global BV
Prinses Margrietplantsoen 33 | Suite 123
2595 AM The Hague
The Netherlands

UDI **506069102UTST5ml50W5**

REF **UTSTT02**

uts™ Urine Testing System

CE UK CA IVD